REMARKS

Applicants have carefully considered this Application in connection with the Examiner's Office Action, and respectfully request reconsideration of this Application in view of the above amendments and the following remarks.

Claims 1-61 are pending in this application.

Claim 54 has been amended to introduce a period at the end of the claim.

I. Claim Rejections under 35 USC §102

The Examiner has rejected Claims 1-6, 12, 13, 15-19, 21, 24, 27, 28, 30-32, 38, 39, 40-44, 46, 49, 52-54, 56, and 58-60 under 35 USC §102 as being anticipated by the Rozaklis Reference (Rozaklis et al. Clinical Chemistry, 2002). The Examiner states that Rozaklis teaches a method for diagnosing a pre-clinical status, or a clinical status of a mucopolysaccharidoses ("MPS") disease in a target patent, and goes on to states that further limitations of the claims are also anticipated.

Applicants respectfully disagree with the Examiner's assessment. The Rozaklis Reference pertains to determination of oligosaccharides in Pompe disease (see title, and abstract, line 15), which is a distinct disease with distinct underlying properties from MPS. As described in the Rozaklis Reference, "**Pompe disease** (glycogen storage disease type II) is one of >40 genetic diseases referred to as lysosomal storage disorders. **It is characterized by the lysosomal accumulation of glycogen within cells, resulting from the deficiency of the lysosomal enzyme acid α-glucosidase.**"

In contrast, **MPS is characterized by a deficiency in the degradation of mucopolysaccharides**. See Paragraph [0004] of the Specification.

Therefore, the current claims recite a method of diagnosing or characterizing a **different** disease from the disease taught by the Rozaklis Reference. Both Pompe disease and MPS are categorized as lysosomal storage disorders, referring to the presence of an enzyme deficiency

relating to the liposome. However, the underlying causes of the lysosomal deficiency are distinct, and **while Pompe is a result of a deficiency or absence of enzymes responsible for the synthesis and degradation of glycogen, in contrast, MPS occurs as a result of a deficiency or absence of arylsulfatase B, resulting in the prevention of degradation of mucopolysaccharides.**

These disorders are therefore reflective of distinct and different underlying disease states, and have been assigned separate diagnosis codes by the World Health Organization in the International Statistical Classification of Diseases and Related Health Problems. MPS is categorized as 2009 ICD-9-CM Diagnosis 277.5, while Pompe disease is categorized as 2009 ICD-9-CM Diagnosis 271.0.

Bec ause the Rozaklis Reference does not recite a method for diagnosing a pre-clinical status or a clinical status of a mucopolysaccharidoses ("MPS") disease, it does not teach all of the limitations of the current claims. Therefore, it cannot anticipate the current claims.

II. Claim Rejections under 35 USC §103

A. The Examiner has rejected Claims 22, 47, and 57, under 35 USC §103 as being unpatentable over the Rozaklis Reference, stating that it would have been obvious to one of skill in the art to use an internal standard derived from a chondroitinase digestion of chondroitin sulfate having an unsaturated uronic acid at the non-reducing end in the method of the Rozaklis Reference. Applicants respectfully disagree. Because the Rozaklis Reference does not teach a method for diagnosing a pre-clinical status or a clinical status of a mucopolysaccharidoses ("MPS") disease, and instead teaches a method relating to a different and distinct disease (namely, Pompe disease), with a distinct and different underlying biological mechanism, it cannot be said to render the current claims obvious.

B. The Examiner has rejected Claims 7, 23, 25, 26, 33, 48, 50, and 51, under 35 USC §103 as being unpatentable over the Rozaklis Reference in view of the Byers Reference (Byers et al., Molecular Genetics and Metabolism, 1998), stating that it would have been obvious to one of skill in the art that the glycosaminoglycan ("GAG") may be heparan sulfate, dermatan sulfate, keratan

sulfate, or chondroitin sulfate. However, because the Rozaklis Reference does not teach a method for diagnosing a pre-clinical status or a clinical status of a mucopolysaccharidoses ("MPS") disease, and instead teaches a method relating to a different and distinct disease (namely, Pompe disease), with a distinct and different underlying biological mechanism, it cannot be said to render the current claims obvious, either alone or in combination with the Byers Reference.

C. The Examiner has rejected Claim 14 under 35 USC §103 as being unpatentable over the Rozaklis Reference in view of the Leeuwenburgh Reference (Leeuwenburgh et al., The American Physiological Society, 1999), stating that it would have been obvious to one of skill in the art that the target quantity and the reference quantity are normalized to creatinine or another oligosaccharide. However, because the Rozaklis Reference does not teach a method for diagnosing a pre-clinical status or a clinical status of a mucopolysaccharidoses ("MPS") disease, and instead teaches a method relating to a different and distinct disease (namely, Pompe disease), with a distinct and differnt underlying biological mechanism, it cannot be said to render the current claims obvious, either alone or in combination with the Leeuwenburgh Reference.

D. The Examiner has rejected Claims 20, 45, and 55, under 35 USC §103 as being unpatentable over the Rozaklis Reference in view of the Hopwood Reference (Hopwood et al., Biochemical Journal, 1985), stating that it would have been obvious to one of skill in the art to use N-acetylglucosamine-6-sulfate ("GlcNAc6S(d3)") as an internal standard. However, because the Rozaklis Reference does not teach a method for diagnosing a pre-clinical status or a clinical status of a mucopolysaccharidoses ("MPS") disease, and instead teaches a method relating to a different and distinct disease (namely, Pompe disease), with a distinct and different underlying biological mechanism, it cannot be said to render the current claims obvious, either alone or in combination with the Hopwood Reference.

E. The Examiner has rejected Claims 8-11 and 34-37, under 35 USC §103 as being unpatentable over the Rozaklis Reference in view of the Byers Reference and in further view of the Merry Reference (Merry et al., The Journal of Biological Chemistry, 1999), stating that it would have been obvious to one of skill in the art to recognize that the fragments of dermatan sulfate, heparin sulfate, keratin sulfate and chondroitin sulfate comprise combination of iduronic acid (IdoA), N-acetylgalactosamine (GaINAc), uronic acid (UA), glucuronic acid (GlcA) and sulfate (S). However, because the Rozaklis Reference does not teach a method for diagnosing a pre-clinical status or a clinical status of a mucopolysaccharidoses ("MPS") disease, and instead teaches a method relating to a different and distinct disease (namely, Pompe disease), with a distinct and different underlying biological mechanism, it cannot be said to render the current claims obvious, either alone or in combination with the Byers Reference and the Merry Reference.

F. The Examiner has rejected Claim 61 under 35 USC §103 as being unpatentable over the Rozaklis Reference in view of the Byers Reference, the Hopwood Reference, the Leeuwenburgh Reference, and the Merry Reference, stating that the combination of the references meets all of the limitations of the current claims. However, because the Rozaklis Reference does not teach a method for diagnosing a pre-clinical status or a clinical status of a mucopolysaccharidoses ("MPS") disease, and instead teaches a method relating to a different and distinct disease (namely, Pompe disease), with a distinct and different underlying biological mechanism, it cannot be said to render the current claims obvious, either alone or in combination with the Byers Reference, the Hopwood Reference, the Leeuwenburgh Reference, and the Merry Reference.

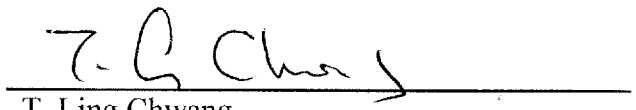
For all of these reasons, Applicants respectfully submit that the current claims would not have been obvious to one of skill in the art at the time the invention was filed.

III. Conclusion

Applicants respectfully submit that, in light of the foregoing comments, all pending claims are in condition for allowance. A Notice of Allowance is therefore requested.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,



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